UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,144	09/09/2003	David Alexander	IMMR-IMD0002E	1898

60140 7590 04/10/2008

IMMERSION -THELEN REID BROWN RAYSMAN & STEINER LLP
P.O. BOX 640640
SAN JOSE, CA 95164-0640

EXAMINER	
GISHNOCK, NIKOLAI A	

ART UNIT	PAPER NUMBER
3714	

MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,144	ALEXANDER ET AL.	
	Examiner	Art Unit	
	Nikolai A. Gishnock	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,24,25,27,32,33 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,24,25,27,32,33 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the Applicant's response of 1/14/2008, claims 1-16, 18-23, 26, 28-31, 39, & 40 are cancelled. Claims 17, 24, 25, 27, & 32-38 are pending.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second or further locking mechanism of claim 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The limitation recited in claim 37, "wherein the mock anatomical site is functionally coupled to a pivotable torsion tube", is found in independent claim 32, at lines 8-9. Applicant is required to cancel the claim, amend to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24, 25, 33, & 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 recites the limitation "extending through the resiliency-providing material" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claim 25 recites the limitation "wherein the block of resilient material is a block of foam" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 24. Claim 33 recites the limitation "wherein the resiliency-providing material is foam" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 32. Claim 36 recites the limitation "wherein... the housing is a mock torso" in line 2. There is insufficient antecedent basis for this limitation in claim 32.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 17, 24, 32, 35, & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (US 4,907,973 A), hereinafter known as Hon, in view of Carlson et al. (US 5,820,600 A), hereinafter known as Carlson.

8. Hon teaches an apparatus for simulation (an expert system simulator for modeling that is especially useful for training personnel in the medical and related arts, 1:7-9) comprising: a housing (internal arterial modeling device, 7:22-35; see Figure 9, Item 91); a mock anatomical site coupled to the housing having an orifice being configured to receive a peripheral device (mock arterial paths having an inserted mock catheter, 7:50-60; see also Figure 9, Item 90 & Figure 10, Items 96, 96a, 96b, ... 96n & 97), the mock anatomical site being functionally coupled to a resilient hollow member or a pivotable torsion tube extending between the orifice and a sensing assembly, the hollow member being configured to guide the peripheral device from the orifice to the sensing assembly (representative internal model with mock arterial paths and

mock catheter for realistic simulation of both the depth and feel of angioplasty. Sensors track the progress of the inserted catheter. Within or adjacent to the arterial pathway, magnetic ring sensors trace the direction and distance of catheter insertion; and a vessel constricting simulator is positioned in one or more desired locations along mock arterial path, 7:50-8:10) [Claims 17, 24, 32, 35, & 37].

9. What Hon fails to teach is a bracket positioned between the mock anatomical site and the sensing assembly; first retainer; a first ring disposed proximate to the orifice, the first ring being configured to rotate about the first retainer; a first locking mechanism configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position; a second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position, and a hollow member extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly [Claims 17, 24, 32, 35, & 37]. However, Carlson teaches an adjustable trocar valve (the valve is attached to the proximal end of a cannula shaft to form part of an introducer assembly, such as a trocar or a radially expandable introducer, for introducing instruments and viewing scopes through a percutaneous penetration into a patient's body, 4:15-19) having a first retainer (pivot tower, Figures 1 & 4, Item 40); a first ring disposed proximate to the orifice (dialator ring, Figures 1 & 4, Item 50), the first ring being configured to rotate about the first retainer (a second valve member or dialator ring is movably coupled around pivot tower, 7:34-49; also, 4:37-46); a first locking mechanism (holding members, Figures 5A & 5B, Item 110) configured to prevent movement of the orifice when the locking mechanism is engaged in a

locked position (the valve further includes means for securing a proximal portion of the instrument at or near the center of the membrane; the securing means comprises one or more holding members coupled to the first valve member for preventing transverse movement of the instrument relative to the membrane, while allowing axial movement, 4:47-55; thus preventing movement of the membrane, being part of the trocar and trocar stop assembly, e.g. the orifice, when secured, while the instrument is moved), and a bracket (introducer assembly including cannula shaft, Figure 1, Items 2 & 4) positioned between the mock anatomical site and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly (introducer assembly generally includes an elongate shaft or cannula, a handle and a valve assembly; cannula has a proximal end, a distal end, and an axial lumen there between for receiving elongate objects, such as an endoscope and/or surgical instruments for performing a surgical procedure within the patient's body, 7:5-23), and allowing the mock anatomical site to pivot (4:27-55; to allow the mock anatomical site to pivot in a first direction with respect to the bracket, and in a second direction substantially orthogonal to the first direction are understood to be intended uses of the apparatus, and not given patentable weight); and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice (Holding members are biased radially inward by a suitable biasing means, such as a spring, so that members secure the instrument at the center of membrane, 10:13-16; it is understood that the spring exerts a pressure force on the trocar and trocar stop, which is countered by friction from a normal force against the simulated instrument). The trocar and valve assembly of Carlson would be inserted into the mock arterial paths of Hon during a surgical simulation. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included a bracket positioned between the mock

anatomical site and the sensing assembly, a first retainer; a first ring disposed proximate to the orifice, the first ring being configured to rotate about the first retainer; a first locking mechanism configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position, and a hollow member extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice, of the trocar as taught by Carlson, in the mock anatomical site in the apparatus for simulation of Hon, in order to increase the realism and accuracy of the training simulation [Claims 17, 24, 32, 35, & 37],

10. What Hon and Carlson further fail to teach is a second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position [Claim 17]. However, Carlson teaches these elements, at least at 4:37-55 and 7:34-49, as treated above. The court has held that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). In the instant case, support for the finding of a new and unexpected result for using a second retainer, ring, and locking mechanism over the advantages disclosed for the first retainer, ring, and locking mechanism was not found in the applicant's specification. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included a second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position, in the apparatus for

simulation of Hon, in light of the teachings of Carlson, in order to increase the realism and accuracy of the training simulation [Claim 17].

11. Claims 25 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon and Carlson as applied to claims 24 & 32 above, and further in view of Younker (US 5,951,301), hereinafter known as Younker.

12. Hon and Carlson teach all the features of claims 24 & 32, as demonstrated above. What Hon and Carlson fail to teach is where a block of resilient material is a block of foam [Claims 25 & 32]. However, Younker teaches a block of resilient material (synthetic torso, 4:20-34) that is a block of foam (a suitable elastomeric formula for making such a dry suture training procedure pack is a two part expandable urethane foam, 7:19-26). The modeling device of Hon would be formed of the resilient foam taught by Younker, for creating synthetic tissues that have a density, resiliency, and flexibility that approximates the corresponding mammalian tissue and reacts to mechanical forces in a n equivalent fashion. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the block of resilient foam formed into a synthetic torso of Younker to form the internal arterial modeling device of Hon, in light of the teachings of Carlson, in order to more precisely replicate the resiliency and reaction to mechanical forces encountered by a simulated endoscope [Claims 25 & 33].

13. Claims 27 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon, in view of Carlson, as applied to claim 32 above, and further in view of Lang et al. (US 5,480,307), hereinafter known as Lang.

14. Hon and Carlson teach all the features of claim 32, as demonstrated above. Hon teaches where in the housing is a mock torso (internal arterial modeling device, 7:22-35; see also Figure 9, Item 91). What Hon and Carlson fail to teach is wherein the mock anatomical site is a simulated patient head [Claim 27], or a mock face [Claim 36]. However, Lang teaches a training and practice apparatus for simulating and practicing clinical processes, having a model bust with a model head (Figure 1, Items 6 & 7), where the mock head has a face (Figure 2, Item 7), and is a mock anatomical site (FIG. 1 shows the model head in a supine disposition, viz. a working position in which clinical dental or orthodontic processes are carried out in the mouth area; this can take place by means of treatment instruments, which are individual treatment tools or treatment equipment connected to supply hoses, 5:8-30). The mock face of Lang would be mounted on the mock torso of Hon, as taught by Lang, to be used by inserting treatment instruments in the mock anatomical site. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have the mock anatomical site be a mock face, as taught by Lang, in the apparatus for simulation of Hon, as taught by Carlson, in order to increase the realism and accuracy of a simulation of facial surgery [Claims 27 & 36].

15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon, in view of Carlson, as applied to claim 17 above, and further in view of Bailey (US 5,800,179), hereinafter known as Bailey.

16. Hon and Carlson teach all the features of claim 32, as demonstrated above. What Hon and Carlson fail to teach is wherein the peripheral device is a guidewire [Claim 38]. However, Bailey teaches a system for training persons to perform surgical procedures, having a mock surgical instrument (implement), coupled to a movement guide and sensor assembly, which contains a guide wire (the distal end of the implement within the housing is affixed to a

movement guide and sensor assembly; collectively, the framed assembly with components described above, guide wire, and the guide rails form the movement guide and sensor assembly, 5:23-49). One of the endoscopic instruments simulated for insertion into the mock body of Hon would be an implement attached to a guide wire, as taught by Bailey. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have made the peripheral device of Hon a guide wire, as taught by Bailey, in order to restrict the motion of the implement within the housing and provide accurate sensing of the implement relative to that housing [Claim 38].

Response to Arguments

17. Applicant's arguments with respect to claims 17, 24, & 32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai A. Gishnock whose telephone number is (571)272-1420. The examiner can normally be reached on M-F 8:30a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/3/2008
/N. A. G./
Examiner, Art Unit 3714

/Ronald Laneau/
Supervisory Patent Examiner, Art Unit 3714